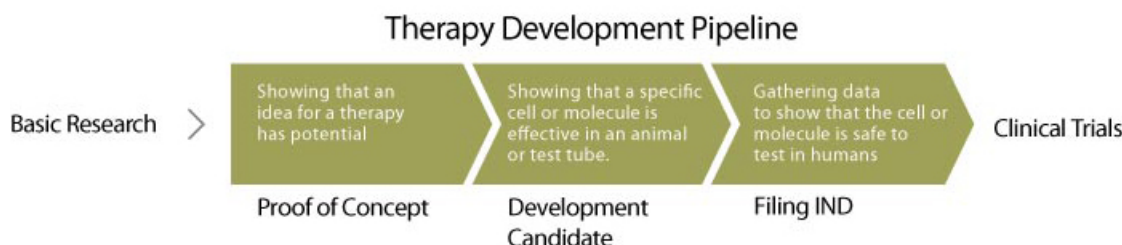


From Lab Bench to Clinic Bedside

How do promising research breakthroughs lead to life-saving treatments? This guide will help you understand the complex path from bench to bedside.



Basic research

The first step toward new therapy, in which scientists learn fundamental information about stem cells, such as how to transform stem cells into brain cells, or insulin producing cells, which could repair a spinal cord injury or treat diabetes. Basic research also focuses on understanding the underlying environment that surrounds stem cells in the body and helps them grow.

Translational research

When scientists take that initial discovery—the ability to mature an embryonic stem cell into a therapeutically useful cell type, for example—and start learning how to turn it into a therapy. Some CIRM translational awards develop animal models for testing stem cell therapies. Others create stem cell models in a lab dish to find drugs that treat Parkinson's disease or autism. Translational research is expected to result in a **proof of concept** for a future therapy, such as a potential drug or a cell type that might prove useful in treating a disease.

Preclinical research

In which scientists take that proof of concept and show that it could really work—at least in animals.

During preclinical research scientists identify a **development candidate**, which is the exact cell or molecule that the team intends to turn into a therapy.

After finding a development candidate, scientists collect data to show the Food and Drug Administration (FDA) that the candidate is safe enough to try in humans. *Collecting this much data is extremely expensive and is frequently not funded by governmental agencies such as the NIH.* CIRM has invested heavily in this stage, because there can be no clinical trials and no therapies if research groups can't collect the safety data they need to begin a clinical trial. This FDA filing is called the **investigational new drug application** (IND).

Clinical Trials

The basic research, translational work and preclinical data collection all lead up to a clinical trial. Clinical trials proceed in three phases:

1. **Phase 1** trials include a very small number of people and are primarily intended to test whether the proposed therapy is safe.
2. **Phase 2** trials include slightly more people and are intended to verify that the therapy is safe, and to start looking into whether it is effective at treating the disease or condition.
3. **Phase 3** trials include large numbers of people and are intended to test whether the therapy treats the disease or condition.

After phase III, the FDA reviews all the data to see if the proposed therapy worked and was safe. **Then, and only then, can it can be used by doctors throughout the country to treat patients.**

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